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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,919	05/19/1999	WILLY MICHEL	6464	5806

25763 7590 08/04/2004

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EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/314,919

Applicant(s)

MICHEL ET AL.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/23/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-17,21-24,27-40,42-54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10,12-17,21-24, 27-40, 42-54 and 56-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. **Claims 10 and 12-15**, drawn to a device for detecting the concentration and/or existence of substances in body fluids of a living body, said device comprising a port body with an elastic self closing diaphragm for accessing the interior of the living body, said port body implantable in the skin of the living body; and a tube extending from the port body into the interior of the living body, the port body and the tube being adapted to allow a detection device to be guided through the tube into the interior of the living body, classified in class 600, subclass 309.
- II. **Claims 16, 17, and 21-24**, drawn to a method comprising the steps of providing a port member containing an elastic closing diaphragm for accessing the interior of a body, said port member implanted in the skin and comprising a feed tube and an aspiration tube extending away from said elastic closing diaphragm and into an interior region of the body; and testing body fluids via said port member. classified in class 600, subclass 156.
- III. **Claims 27-39**, drawn to a device comprising (a) an elastic self closing diaphragm located in a port body implanted in the skin of a body; (b) a feed element associated with the self closing diaphragm, the feed element being suitable for delivery of a

substance into a subject; and (c) an aspiration element associated with the self closing diaphragm, the aspiration element having a second distal end disposed opposite the elastic self closing diaphragm, wherein the aspiration element is suitable for accessing subject fluids, classified in class 604, subclass 43.

IV. **Claims 40 and 42-53**, drawn to a method comprising the steps of accessing a site through an elastic self closing diaphragm associated with an introduction element and contained within a port body implanted in the skin of a living body, (b) analyzing the subject fluids via a first tube disposable within the elastic self closing diaphragm and the introduction element, classified in class 600, subclass 309.

V. **Claims 54 and 56-62**, drawn to a method comprising the steps of (a) accessing a site through an elastic self closing diaphragm implanted in the skin of a living body; (b) delivering a substance to the site via a feed element associated with the elastic self closing diaphragm; and (c) analyzing the subject fluids via an aspiration element associated with the elastic self closing diaphragm, classified in class 604, subclass 43.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I

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and III have separate utility in view of the structural differences disclosed above.

See MPEP § 806.05(d).

Inventions II, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the cited methods include steps that suggest different modes of operation, functions, and effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

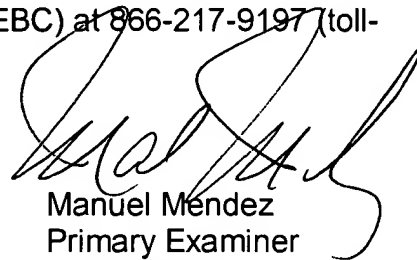
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM